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OBJECTIVES: In chronic diseases, health-related quality of life (HRQoL), a key health outcome measure, varies not just between- but also within-individual patients over time due to acute changes in clinical or environmental circumstances. Cross-sectional assessments of HRQoL consider only between-patient differences and do not reflect within-patient changes, which require multiple assessments over time. This study aims to disaggregate the between- and within-individual factors influencing HRQoL over time in persons with hemophilia A. **METHODS:** In a two-year observational prospective study of health care utilization and burden of illness in US hemophilia A patients (HUGS Va), the SF-12 (adults) and PedsQL (children aged <18 years) was used to assess HRQoL at baseline, 6, 12, 18 and 24 months. Information was also collected about disease severity, sociodemographic variables, annual bleeding and emergency room visits frequencies and missed days from work/school. **RESULTS:** Only small variations in HRQoL were observed over time in the entire study population of 157 adults and 164 children, of which 64.6% have severe disease. At baseline, 6, 12, 18 and 24 months, adult mean mental component scores were 50.9±10.1, 49.8±9.7, 50.2±10.2, 49.5±10.6 and 50.4±9.5 respectively, while mean physical component scores were 43.4±10.7, 43.3±10.8, 50.2±10.2, 49.5±10.6 and 50.4±9.5 respectively. Among children, mean psychosocial functioning scores at each follow-up were 84.1±15.3, 83.3±13.3, 80.3±15.6, 83.5±16.0 and 82.9±13.2 respectively, while mean physical functioning scores were 89.5±15.2, 85.5±17.8, 82.7±22.3, 85.7±18.0 and 84.7±17.3 respectively. After plotting the HRQoL scores of individuals over time, however, greater variations in the magnitude and pattern of fluctuation can be observed, reflecting acute within-patient changes. **CONCLUSIONS:** HRQoL fluctuates over time on the individual level, but not at the study population level as aggregation of scores to the mean masks individual variation. In order to identify factors influencing changes in HRQoL across time, multivariate multilevel modelling will be employed to disaggregate between- and within-individual differences in HRQoL.

PSY68

HEALTH-RELATED QUALITY OF LIFE IN A PORTUGUESE COHORT OF PATIENTS WITH SYSTEMIC LUPUS ERYTHEMATOSUS

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OBJECTIVES: To analyse the impact of systemic lupus erythematosus (SLE) on Portuguese patients' quality of life. **METHODS:** Study conducted in one Portuguese hospital with a Auto-immune Disease Unit, sample size were 116 patients with SLE. All patients fulfilled the American College of Rheumatology (ACR) 1997 revised criteria for the classification of SLE and the date at which the fourth SLE classification criterion was observed was recorded as the date of diagnosis. Patients were grouped into 3 distinct phenotypes namely neuro-psychiatric (NPSLE), nephritis and non-NPSLE non-nephritis sub-groups. Quality of life measured through SF-36 and EQ-5D. Questionnaires were sent by mail and participation was voluntary and confidential. **RESULTS:** Sixty eight per cent valid answers were received (n=79). Respondents were predominantly female (89%) with average age 45 years. In these, the average length of disease was 12.3 (±8.7) years. Average ACR criteria was 5.1 (±1.26) Quality of life measured through EQ-5D was 0.61 (±0,32) with a large majority of answers between 0,5 and 1,0. The average value for SF-36 mental component was 65 and the physical component was 66. **CONCLUSIONS:** Age was negatively correlated at a significant level with results obtained for EQ-5D and the physical component of SF-36. Disease duration was also negatively correlated at a significant level with the physical component of SF-36. Correlation between QoL instruments was found to be in accordance with studies in other countries. QoL measured through SF-36 was consistently lower than the Portuguese norm. Results of QoL in Portuguese patients with SLE found to be comparable to the scarce available evidence in other countries. For both instruments Portuguese patients with SLE reported worst HRQoL than Portuguese patients with psoriasis.

SYSTEMIC DISORDERS/CONDITIONS – Health Care Use & Policy Studies

PSY70

PHYSICIAN PERSPECTIVES ON MANAGEMENT OF PATIENTS WITH SYSTEMIC LUPUS ERYTHEMATOSUS (SLE): RESULTS FROM A CROSS-SECTIONAL SURVEY IN THE UNITED STATES

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OBJECTIVES: To characterize physician practice patterns and their approaches towards assessment and management of SLE patients in usual practice settings in the United States. **METHODS:** Actively practicing rheumatologists with >= 3 years of treating SLE were recruited from a panel of > 4,000 rheumatologists in the U.S. Physicians completed an online survey covering SLE practice patterns, viewpoints and patient communication approaches. Descriptive analyses were conducted on the overall sample; subgroups were compared using chi-square and t-tests, as appropriate. **RESULTS:** Between February and April 2012, 304 physicians from 42 states completed the survey [68% male; mean age: 49; 69% community/non-academic; 69% Caucasian)]. Physicians treated SLE patients for a mean of 16 years. Mean(SD) time spent by physicians with patients was 52(15) minutes at initial visit and 22(7) minutes at follow-up visits. Overall distribution of SLE disease severity was 46% mild, 37% moderate, and 17% severe. 73% of patients had adequately controlled SLE; and 20% were on moderate to high dose of steroids. While 64% of physicians reported involving patients in treatment decisions 'often/very often', physicians were evenly divided (52% vs. 48%) in whether doing so does or does not 'improve outcomes a lot'. A greater proportion of physicians in the former group believed that (a) patient knowledge of clinical tests helped improve adherence (51% vs. 32%; p=0.001); b) SLE has a very high impact on patient quality of life (27% vs. 17%; p=0.002); c) had greater satisfaction with patient interactions (8 vs. 8.4; scale 0-10; p=0.007); and reported setting goals with their patients (78% vs. 68%; p=0.05). **CONCLUSIONS:** Approximately half of surveyed physicians believe that involving patients in treatment plans is important to attaining favorable outcomes. This belief corresponds to a greater appreciation of doctor-patient interactions. Its impact on SLE outcomes and factors influencing this belief warrant further research.

PSY71

APPROACHES TO PAIN MANAGEMENT AMONG OLDER AND YOUNGER ADULTS EXPERIENCING MODERATE TO SEVERE PAIN IN A NATIONAL HEALTH SURVEY: TOO MUCH OR NOT ENOUGH?

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OBJECTIVES: To describe pain management among older adults reporting moderate to severe pain and to evaluate the extent to which polypharmacy in pain management is associated with greater medication side effects. **METHODS:** The 2011 US National Health and Wellness Survey was used. Participants completed a self-administered, internet-based questionnaire, reported pain medications (e.g. specific medication, duration of use, days used in past month) grouped by number of prescriptions used (0, 1, ≥ 2) and the World Health Organization Pain Ladder guidelines. Participants were at least 65 years of age. Analyses were appropriately weighted for the complex survey design. **RESULTS:** Of the 16,500 participants ≥65 years of age, 35.9% reported pain in the past 12 months, with 66% reporting moderate/severe pain. The most common sources of pain were: arthritis pain (66.1%), back problems (58.5%), and joint pain (55.3%). Daily pain was reported in 60%. Among older adults experiencing moderate/severe pain, 50% received no prescription pain medication, 32% received one prescription, and 18% received ≥ 2 prescriptions for pain. Relative to one prescription, those reporting ≥ 2 prescriptions received stronger analgesics (WHO level 3: 28.3% vs. 8.2% for ≥ 2 vs. 1; WHO Level 2: 55.0% vs. 45.2% for ≥ 2 vs. 1). Use of adjuvants to pain medications were more common in those with ≥ 2 relative to 1 pain medication. Compared to participants on 1 prescription pain medication reporting at least one side effect (n=194), participants on ≥ 2 pain medications reporting at least one side effect (n=197) were significantly more likely to report bloating (11.0% vs. 6.8%), nausea (16.5% vs. 5.1%), trouble thinking clearly (19.0% vs. 6.7%), and sleepiness (47.5% vs. 25.6%). **CONCLUSIONS:** Moderate/severe pain is common among older adults, and for most, occurs daily. Pain management appears to be suboptimal and may include polypharmacy in pain management as well as under-treatment of pain.

PSY72

GAINING A PRODUCT ORPHAN DESIGNATION IS NOT INDICATIVE OF IMPROVED MARKET ACCESS SUCCESS IN EUROPEAN COUNTRIES

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OBJECTIVES: Within the EU, pharmaceutical products in development may apply for an orphan product designation if the product can demonstrate potential value in a rare disease indication. Not all products used in rare diseases apply for or receive such a designation. The research question posed was whether gaining an orphan drug designation in the EU is indicative of a rare disease product achieving greater market access success. **METHODS:** Products receiving an EU Marketing Authorisation (MA) between 2009-2011 with an orphan designation were compared with those that were approved for at least one indication of use in a rare disease. Indicative markers of market access success were reviewed, including outputs of product evaluation recommendations from the Scottish Medicines Consortium and HAS in France. Additionally, 16 payers in 4 European countries were interviewed for qualitative insights on how an orphan designation would impact on their evaluation of price. **RESULTS:** Fourteen (14) products with orphan-product designation received an EU MA during 2009-2011. Twenty (20) products without orphan-designation but with at least one indication for a rare disease received an EU MA during 2009-2011. Forty two (42)% of the orphan designated products gaining an EU MA received a recommendation for use in Scotland, with 67% of non-orphan designated products indicated for a rare disease receiving a recommendation for use. Ninety two (92)% of the orphan designated products were included on the reimbursement list in France, with 89% of non-orphan designated products included on the reimbursement list. Payers indicated that orphan drug status is methodologically difficult to consider in relation to price, but it may have other relevant market access benefits. **CONCLUSIONS:** For products with an MA for treating rare diseases, the analysis performed concluded that products receiving an EU orphan drug designation did not demonstrate greater market access success in the selected EU countries using the applied criteria.

PSY73

LOW AVAILABILITY OF ORPHAN MEDICINES IN SERBIA

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OBJECTIVES: In the European Union (EU), rare diseases are defined as life-threatening or chronically debilitating diseases with prevalence lower than five